REMARKS

The office action dated January 9, 2006 has been carefully reviewed. Claims 1-13 are pending in this application. Claims 11 and 12 have been withdrawn. Reconsideration of this application is respectfully requested.

CLAIM REJECTIONS BASED ON §103 – DEVANATHAN/RAAB

Claims 1-10 and 13 were rejected under 35 U.S.C. §103 as being obvious over U.S. Patent No. 5,645,594 issued to Devanathan et al. (hereinafter "Devanathan") in light of U.S. Patent No. 6,136,058 issued to Raab (hereinafter "Raab"). Applicants respectfully traverse this rejection. Reconsideration of claims 1-10 and 13 is respectfully requested.

In the 2/9/06 Office Action, the Examiner indicated:

> "Devanathan et al, however, do not teach using a copolymer of ethylene and acrylate. Raab teaches forming an implantable bearing having a layer of copolymer that increases the adhesion of the bearing to a bone via bone cement. Raab also teaches using a copolymer of a biocompatible plasticizer and PMMA as the copolymer that increases adhesion (col 3, lns 5-12). ***Devanathan et al and Raab are combinable because they are analogous with respect to forming an implantable bearing.*** Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made ***to substitute a layer of UHMWPE/PMMA copolymer for the blended layer of Devanathan et al as taught by the general teaching of Raab in order to form a layer that increases adhesion while increasing strength***." (emphasis added).

Apparently, the Examiner is proposing to substitute the PMMA film from Raab for the dry blended mixture of UHMWPE and PMMA of Devanathan. As will be discussed below, this proposed combination is legally flawed for numerous reasons.

It is a fundamental tenet of patent law that a prima facie case of obviousness cannot be established in the absence of some teaching, motivation, or suggestion supporting

the modification or combination of the references relied upon in making the rejection. The rule of law for a finding of obviousness under 35 U.S.C. § 103(a) was reiterated recently by the Court of Appeals for the Federal Circuit as follows, "[w]hen patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness." In re Lee, 277 F.3d 1338 at 1343, 61 USPQ2d 1430 (Fed. Cir. 2002). The teaching or suggestion to make the claimed combination must be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

In an apparent attempt to establish a case of obviousness in the present case, the Examiner stated that it would have been obvious to substitute the PMMA film from Raab for the dry blended mixture of UHMWPE and PMMA of Devanathan "*in order to form a layer that increases adhesion while increasing strength*". This conclusory, unsupported statement is insufficient for a number of reasons. Firstly, for a teaching, motivation, or suggestion to be proper it must come from the prior art. In this regard, the Examiner has not identified where the prior art identifies the purported teaching, motivation, or suggestion that supports the need to substitute Devanathan's dry blended mixture. In other words, contrary to the Examiner's assertion, there is no passage in Raab or Devanathan that purports that either "adhesion" or "strength" is increased by using Raab's method relative to the

Devanthan's method. Indeed, the Examiner pointed to column 3, lines 5-12 of Raab for support for the notion that use of "a copolymer of biocompatible plasticizer and PMMA as the copolymer increases adhesion." However, this passage is merely contrasting use of such a copolymer over its inventor's previous work where the plasticizer was apparently not used. This statement in no way suggests that Raab's film increases adhesion relative to all other methods of incorporating PMMA into bearings, and certainly doesn't suggest that it is any better than the teachings of Devanathan. In fact, a careful reading of Raab makes it clear that proper adhesion of the PMMA film can only occur if significant steps are taken to prepare the implant prior to application of the film. See, for example, column 5, line 40 through column 7, line 15 where nearly two full columns of discussion are dedicated to the numerous steps such as degreasing, acid etching, rinsing, and so on that must be performed prior to application of the PMMA film. Equally complex preparations are necessary before securing the PMMA film to a polymer component – see, e.g., column 10, lines 1-38. There is no indication in Raab that the PMMA film is any better adhered to the remainder of the bearing than is the co-molded PMMA polymer of Devanathan. To the contrary, one can argue that the extensiveness of the pre-adhesion preparation of Raab's bearing suggests a fickleness to the PMMA film's adhesiveness, NOT an "increase" relative to other dissimilar methods such as Devanathan's.

The Examiner attempted to supplement his argument by asserting that "*Devanathan et al and Raab are combinable because they are analogous with respect to forming an implantable bearing.*" This statement alone or in combination with the unsupported, conclusory statement discussed above cannot form a basis for a proper rejection. Indeed, the mere fact that both Devanathan and Raab are directed to orthopaedic bearings cannot, *ipso facto*, function as motivation to combine them. Under this logic, for no other reason at all, every reference related to orthopaedic bearings would necessarily be

properly combinable with every other reference related to orthopaedic bearings. This simply isn't the case.

Furthermore, not only has the Examiner not offered a legally sufficient teaching, motivation, or suggestion to combine Devanathan and Raab, it is believed that no such motivation exists since to do so would destroy the intent of the invention of Devanathan. Indeed, Devanathan is directed to a method of incorporating PMMA into a UHMWPE bearing by utilizing a mixture of UHMWPE and PMMA that is dry blended together before molding. See column 1, lines 35-58 where it is described that the use of such a mixture is the very object of Devanathan's invention (emphasis added):

> This invention provides for an acetabular cup and the manufacturing of an acetabular cup implant formed from a composite of polymer materials such that the articulating surface of the implant is 100% ultra high molecular weight poly ethylene (UHMWPE) and the bone engaging surface of the cup is essentially poly methyl methacrylate (PMMA). The cup would consist of at least two zones. Zone 1 forming the articulating surface and zone two extending from the zone 1 to the bone engaging surface. Preferably, the zone 1 would consist of UHMWPE and would extend a predetermined thickness from the articulating surface. **Zone 2 would preferably consist of a mixture of UHMWPE and PMMA dry blended before molding**. A third zone would consist essentially of PMMA.
>
> **Another object of the invention is to provide for an prosthetic acetabular cup having a substantial portion of the cup *formed from a mixture* of PMMA and UHMWPE.**
>
> **Another object of the invention is to provide for an acetabular cup having a layer of UHMWPE forming an articulating surface and a body *formed from a mixture* of PMMA and UHMWPE.**

With this in mind, one skilled in the art would not be motivated to use the PMMA copolymer film of Raab since the whole point of the Devanthan method is to use a <u>mixture</u> of PMMA and UHMWPE. In other words, to use the copolymer film of Raab would destroy Devanathan's invention. The CCPA and the CAFC have consistently held that when a

Section 103 rejection is based upon a modification of a reference that destroys the intent, purpose, or function of the invention disclosed in the reference, such a proposed modification is not proper and a *prima facie* case of obviousness cannot be properly made. There can be no finer example of the application of this standard than the proposed use of Raab's copolymer film as a substitute for Devanathan's blended mixture.

Because the Examiner has not offered a legally sufficient teaching, motivation, or suggestion to combine Devanathan with Raab, and in light of the overwhelming reasons against such a modification, it appears that the Examiner is using the Applicants' application as a roadmap in developing his rejection. That is, the Examiner appears to be using hindsight reconstruction as a substitute for a factual basis for the rejection of the claims under 35 U.S.C. §103. Such use of hindsight reconstruction is not proper. "There must be a reason apparent at the time the invention was made to a person of ordinary skill in the art for applying the teaching at hand, or the use of the teaching as evidence of obviousness will entail prohibited hindsight." *In re Nomiya, Kohisa, and Matsumura*, 509 F.2d 566, 184 USPQ 607 (CCPA 1975). "The Patent Office has the initial duty of supplying a factually basis for a rejection under 35 U.S.C. § 103. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis." *In re Rice*, 481 F.2d 1316, 178 USPQ 478, 479 (CCPA 1973).

Even if, for arguments sake, the Examiner had provided a legally sufficient teaching, motivation, or suggestion for combining Devanathan and Raab, the rejection is still unsupported by the art. Indeed, contrary to the Examiner's assertion on page two, last four lines of the 2/09/06 Office Action that Raab teaches "a layer of UHMWPE/PMMA copolymer", it does not. Raab teaches use of a PMMA/plasticizer copolymer, most notably,

a PMMA/HEMA copolymer. There is no teaching of a UHMWPE/PMMA copolymer. As a result, the rejection is unsupported by the art and should be withdrawn.

As a result of the above, the Examiner has not established a prima facie case of obviousness with regard to Applicants' claims 1-10 and 13. As such, the rejection of claims 1-10 and 13 should be withdrawn.

CONCLUSION

In view of the foregoing, it is submitted that this application is in a condition for allowance. Action to that end is hereby solicited.

It is respectfully requested that this paper be considered as a TWO-MONTH Petition for an Extension of Time sufficient to effect a timely response. Please charge the fee for this extension of time, as well as any additional fees in connection with this response, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 265280-68188.

Respectfully submitted,

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